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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,090	Applicant(s) HAREL, MOTI	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-123 is/are pending in the application.
- 4a) Of the above claim(s) 101, 102, and 117-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-100, 103-116 and 121-123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments and arguments filed May 14, 2009 are acknowledged and have been fully considered. Claims 87-123 are now pending. Claims 87, 90-95, 100, 103, and 121 are amended; claims 101, 102, and 117-120 are withdrawn; claim 123 has been added. Claims 1-86 are cancelled. Claims 87-100, 103-116, and 121-123 are the subject of this Office Action.

OBJECTIONS/REJECTIONS WITHDRAWN

The objection to claim 95 is withdrawn in light of the claim amendments.

The rejections of claims 87-100 and 103-116 under 35 U.S.C. 112, 2nd paragraph are withdrawn in light of the claim amendments.

The rejection of claims 121 and 122 under 35 U.S.C. 102(b) over LEE is withdrawn upon further consideration.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claim 95 under 35 U.S.C. 112, 1st paragraph, lack of written description, is maintained as discussed below.

The rejection of claims 121 and 122 under 35 U.S.C. 102(b) over NAKATSUKA are maintained as discussed below.

The rejection of claims 87-96, 98, 103, 104, 108-112, and 114 under 35 U.S.C. 103(a) over KÜRZINGER and NAKATSUKA is maintained as discussed below.

The rejection of claims 87, 97-100, 103, 105-107, 113, 115, and 116 under 35 U.S.C. 103(a) over KÜRZINGER, NAKATSUKA, and VILLAMAR is maintained as discussed below, and is further applied to new claim 123.

Claim Rejections - 35 USC § 112 (1st Paragraph) (Maintained)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claim 95 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 95 recites "derivatives" of starch.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written

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description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106). See MPEP § 2163.

Applicant has failed to provide any further description of the various derivatives as recited in instant claim 95 that would provide adequate written description of the compounds encompassed by the claim. Adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties. Applicants provide no direction as to what subset of derivatives out of all possible derivatives that exist in the art would possess the required properties and be useful to form a controlled-release particle with alginate. The term "derivatives" is extremely broad and encompasses, for example, salt forms, reaction products, and degradation products. It is noted that in the present case, no examples of the claimed derivatives are provided or described. The skilled artisan would have been unable to readily envision the chemical structures of the claimed subject matter (i.e. the entire genus encompassed by the claim). Thus, the disclosure fails to describe the claimed compounds in a manner that complies with the written description requirement of 35 U.S.C. 112, 1st Paragraph.

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that starch derivatives were known in the art and that a skilled artisan would have been able to determine an applicable starch derivative (response, p. 6-7).

It is noted that no actual evidence was presented to support applicant's assertion that starch *derivatives* were well known in the art. The examiner agrees that modified starches have been assigned INS codes as stated by applicant. The recognition of this term in the art precluded the 112 1st paragraph rejection of the term "modified starch". However, the scope of the term "derivatives" goes far beyond the limited number of starches recognized as "modified starches", hence the written description rejection. Since starch derivatives were recited in claim 95 separately from modified starches, an ordinary artisan would recognize that the term must mean something different. It is reiterated that no examples of starch derivatives were presented or even mentioned in the specification. The term "derivatives" is extremely broad and encompasses, for example, salt forms, reaction products, and degradation products. Glucose, and heteropolymers comprising glucose, for example, would qualify as starch derivatives. Yet, applicant provides no direction as to what subset of derivatives out of all possible derivatives that exist in the art would possess the required properties and be useful to form a controlled-release particle with alginate.

Applicant further argues that functional language has been added to the claim to satisfy the written description requirement (response, p. 7).

The test for written description is not whether the skilled artisan would be able to determine an applicable starch derivative after the fact, but rather whether applicant was in possession of the full scope of the claim at the time of the invention. The lack of the mere mention of starch derivatives in the specification stands as evidence that applicant did not know at the time of the invention what starch derivatives would be useful in the invention. Moreover, the alleged "functional language" currently added to claim 95 is insufficient to satisfy the written description requirement. The MPEP states that, "An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613. Applicant has attempted to define starch derivatives by a property without any discussion of known or disclosed correlation between function and structure of such derivatives, and has presented no evidence that an artisan would have recognized any functional correlation between the structure of certain starch derivatives and the claimed property. Further, the newly added limitation, "...wherein dissolved starch granules are formed when the starch complexes with the emulsifier in alkali solution", does not specifically limit the term "starch derivatives". Thus, a skilled artisan would not have been apprised of what starch derivatives would be useful in the invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 121 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by NAKATSUKA (U.S. 4,076,846; Issued Feb. 28, 1978).

1. Nakatsuka discloses edible starch compositions for use in feedstuffs, agriculture, and fisheries (abstract). Nakatsuka discloses granules (i.e. particles) comprising alginate, high-amylose starch (i.e. a non-digestible polymer as set forth in the instant specification), and lecithin (i.e. an emulsifier) (col., 15, Table 4, Example 8), reading on claim 121. The particles described in Example 8 comprise casein (i.e. a protein), glycerol, and sorbitol, any one of which qualifies as a bioactive agent per the description of bioactive agents in the instant specification (paragraph [0039]). In addition to the category of proteins (of which casein is a member), suitable bioactive agents are stated to include drugs. Both glycerol and sorbitol have been used as laxatives, and thus may fall into the broad category of drugs. Thus, Nakatsuka anticipates claim 122.

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that Nakatsuka does not anticipate the claimed invention because applicant alleges that Nakatsuka does not teach a particular starch-emulsifier complex (response, p. 7).

It is noted that the term "complex" has not been given a special definition in the instant application. Thus, the term can be interpreted broadly. Webster's dictionary defines a "complex" as, *inter alia*, 1) an association of related things often in intricate combination, and 2) a conjunction of varied contributing or interacting factors, elements, or qualities. The compositions of Nakatsuka, which comprise alginate, high-amylose starch, and lecithin (i.e. an emulsifier) (i.e. all the components required of the instant compositions) fall within this definition and thus can be considered to comprise a starch-emulsifier complex.

Applicants argue that Nakatsuka does not teach a method to prepare a particular starch-emulsifier complex (response, p. 8).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a method to prepare a starch-emulsifier complex by dissolving the starch in an alkali solution and adding an emulsifier to this solution) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, it is noted that applicant has not elected a process. Rather, in the correspondence dated Oct. 27, 2008, applicant elected Group I, drawn to an animal feed *composition*.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 87-96, 98, 103, 104, 108-112, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over KÜRZINGER (U.S. 6,303,175; Issued Oct. 16, 2001) in view of Nakatsuka.

2. Kürzinger discloses particulate feeds for aquatic animals, especially fish, shrimps, and invertebrates (abstract; col. 2, line 65; col. 3, lines 19-25; claims 12 and 13). The preferred feed contains 0.001-50%, of a gel forming compound or compounds

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that may be alginate in combination with other polymers such as, *inter alia*, starches, cellulose materials, guar gum, or gum arabic (abstract; col. 2, lines 17-26). 0.1-10% of the gel forming component(s) is especially preferred (abstract; col. 1, line 67 to col. 2, line 3; claims 1-5). Examples of the gel forming component(s) present in the range of 1.5-5.5% are provided (col. 3, lines 50-58, Variant 1). These percentages are taught with respect to compositions comprising particular water contents (e.g. 50-99% or 73-94% water) (abstract; col. 2, line 3; col. 3, lines 50-58, Variant 1), and are thus wet weights. Kürzinger specifically teaches that the gel formers can be used alone or preferably in synergistic combinations, improving the acceptance and properties of the feed (col. 2, lines 32-34). Kürzinger teaches the inclusion of emulsifiers such as lecithin for the improvement of consistency and binding of the feed mixture (col. 2, lines 44-50). Kürzinger also teaches that the compositions can be treated by drying (col. 3, lines 19-23).

3. Kürzinger does not specify a suitable weight ratio of emulsifier to the non-digestible polymer. The ordinary artisan would have looked to the literature for guidance regarding appropriate amounts of emulsifier to include in the composition.

4. Nakatsuka discloses edible particulate compositions for use in feedstuffs, agriculture, and fisheries (abstract). Nakatsuka discloses granules (i.e. particles) comprising alginate, high-amylose starch (i.e. a non-digestible polymer as set forth in the instant specification), and lecithin (i.e. an emulsifier) (col., 15, Table 4, Example 8). Nakatsuka teaches that lecithin is particularly suitable for use with starch materials because it has a desirable affinity toward starch and has an adequate hydrophilic-

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lipophilic balance (col. 7, lines 59-63). Furthermore, Nakatsuka teaches that up to 10% by weight or more of lecithin can be added, as embodied in examples 7-9 and 20-23 (col. 7, line 65 to col. 8, line 6). Nakatsuka also teaches that a composition containing about 10% by weight lecithin has favorable release properties (col. 7, lines 66-68). While it is noted that only 1 part by wet weight lecithin is exemplified in examples 7-9, the teaching of up to 10% lecithin is clear, and one of ordinary skill in the art would have recognized the advantages of the release properties in the feed production process as taught by Nakatsuka.

5. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to utilize from 1% up to 10% wet weight lecithin, in the composition of Kürzinger to provide a particulate feed composition having favorable release properties per the teachings of Nakatsuka. One would have been motivated to do so since Nakatsuka teaches that lecithin is particularly suited to similar feed compositions comprising starch, and since Nakatsuka teaches that such amounts are advantageous. Further, one would have had a high expectation of success in doing so since Kürzinger teaches the use of both starch and lecithin in the feed compositions (col. 2, lines 23 and 50; claim 3).

6. Based on the teachings of Kürzinger the ordinary artisan would have a high expectation of success in combining alginate and any of several non-digestible polymers. The artisan would be guided by Kürzinger's teaching of using a combination of these polymers wherein each could be present in amounts such that the total of the two polymeric components is between about 5.5% and 10% wet weight. Thus, the

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inclusion of lecithin at the levels taught by Nakatsuka would result in compositions wherein the emulsifier (i.e. lecithin) is present in a ratio of between about 1:2 relative to the non-digestible polymer. It is well within the skill of the ordinary artisan to optimize the precise amounts of these components, particularly given the relatively narrow teachings of Kürzinger and Nakatsuka. Furthermore, there is nothing of record to show the criticality of the claimed percentage ranges. Therefore, the combination of Kürzinger and Nakatsuka reads on claims 87-95, 103, and 104.

7. As discussed above, under 102 rejections Nakatsuka teaches proteins and other components that qualify as bioactive agents based on the examples provided in the specification. It is noted that the terms "microstructure" and "nanostructure" have not been given special meaning in the specification. Thus, these terms have been interpreted broadly, and encompass the natural feed components disclosed by Kürzinger, such as zooplankton. Furthermore, zooplankton are microbes (i.e. microscopic organisms) (elected species), and are clearly bioactive agents as defined in claim 98. Thus, the combination of Kürzinger and Nakatsuka reads on claim 96 and 98. Both Kürzinger and Nakatsuka disclose compositions comprising glycerol (see col. 2, lines 35-38 of Kürzinger), which is classified by the FDA as a caloric macronutrient, reading on claim 108.

8. While the feed taught by Kürzinger is intended for aquatic animals, the ordinary artisan would readily envisage the possibility of its administration to humans, particularly, in light of Nakatsuka's teaching that the components of the composition should have no harmful effect on the human body (col. 7, lines 41-46). Since many of

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the species raised in aquaculture are intended for human consumption, the compositions must also be acceptable for human consumption as would be recognized by the ordinary artisan. Thus, the combination of Kürzinger and Nakatsuka renders claim 109 obvious.

9. As noted *supra*, the feed taught by Kürzinger is for aquatic animals, especially fish, shrimp, and invertebrates (abstract). Further Kürzinger teaches the use of the disclosed feed for ornamental fish in an aquarium (i.e. domestic animals). Since Nakatsuka teaches that the components of the composition should have no harmful effect on the human body, one of ordinary skill in the art would readily have envisioned humans as a target animal for the feeds of the invention, particularly since many of the aquaculture species for which these feeds are intended are raised for human consumption, either directly or indirectly. Thus, the combination of Kürzinger and Nakatsuka renders claims 110-112 and 114 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention

as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that Kürzinger does not teach the production process disclosed in the present application (response, p. 10).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a process of preparing a starch-emulsifier complex by dissolving the starch in an alkali solution and adding an emulsifier to this solution) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, it is noted that applicant has not elected a process. Rather, in the correspondence dated Oct. 27, 2008, applicant elected Group I, drawn to an animal feed *composition*.

It is noted that the term "complex" has not been given a special definition in the instant application. Thus, the term can be interpreted broadly. Webster's dictionary defines a "complex" as, *inter alia*, 1) an association of related things often in intricate combination, and 2) a conjunction of varied contributing or interacting factors, elements, or qualities. The compositions of Kürzinger and Nakatsuka, which comprise alginate, high-amylose starch, and lecithin (i.e. an emulsifier) (i.e. all the components required of the instant compositions) fall within this definition and thus can be considered to

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comprise a starch-emulsifier complex.

Regarding claim 95, the newly added limitation, "...wherein dissolved starch granules are formed when the starch complexes with the emulsifier in alkali solution" is intended use. This limitation merely requires that the starch be capable of dissolving in an alkali solution with an emulsifier and does not limit the production of the recited starch-emulsifier complex. See MPEP § 2106, which states, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." Statements of intended use are one category of language that raises a question as to the limiting effect of the language in a claim.

Applicant argues that there is no suggestion to combine Kürzinger and Nakatsuka (response, p. 10).

Both Kürzinger and Nakatsuka are concerned with similar problems in the art. Specifically, Kürzinger discloses particulate feeds for aquatic animals, especially fish, shrimps, and invertebrates and Nakatsuka discloses edible particulate compositions for use in feedstuffs, agriculture, and fisheries. By applicant's own admission both references are concerned with molded feed compositions. Thus, there is sufficient motivation for a skilled artisan to look to both of the cited references.

Claims 87, 97-100, 103, 105-107, 113, 115, and 116 and now applied to new claim 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kürzinger in view of Nakatsuka as applied to claims 87-96, 98, 103, 104, 108-112,

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and 114 above, and further in view of VILLAMAR (WO 02/00035; published Jan. 3, 2002).

10. The teachings of Kürzinger and Nakatsuka have been presented *supra*. It is noted that applicant has defined "controlled release" delivery systems to include systems manipulated to assure that the materials within a particle are delivered intact to the desired location (paragraph [0046]). Based on this definition, the particles of Kürzinger also provide controlled release since they allow the materials within the particles (i.e. the natural feed components) to be delivered intact to the desired location, that being the stomach of the animal. Additionally, Kürzinger teaches the use of a variety of natural feed components, but does not explicitly teach the inclusion of the microbes recited in claims 99-100. Kürzinger does not teach the particle sizes recited in claims 105 and 106 and does not teach bioattractants.

11. It is noted that alginate-containing beadlets and particles for aquaculture use are well known in the art and many are used as controlled release compositions. For example, Villamar discloses a bioactive food complex in the form of particles or microcapsules that comprise alginate and other non-digestible polymers as well as emulsifiers such as lecithin (p. 10, 2nd and 3rd paragraphs; p. 14, 3rd paragraph; p. 16, 2nd paragraph). These feed particles serve to deliver different bioactive components to the digestive tract (such as the intestines) of animals such as shrimp or fish or other livestock raised commercially to control bacterial disease in such livestock (abstract, p. 7, 2nd paragraph). Thus, the compositions of Villamar are controlled release compositions for the bioactive agent(s) incorporated therein. Villamar teaches the

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inclusion of probiotic bacteria in the compositions of the invention (abstract), and teaches that *Bacillus* sp., *Lactobacillus* sp., and other bacteria are probiotics commonly added to feeds in the animal agriculture industry (p. 6, last paragraph). Villamar specifically teaches the use of, *inter alia*, *Bacillus subtilis*, *Bacillus licheniformis*, and *Lactococcus lactis* (p. 6, 3rd paragraph; claim 6).

12. One of ordinary skill in the art would recognize that the animal agriculture industry includes such feedstock animals as mollusks, rotifers, and artemia. Furthermore, Villamar teaches adjusting the size and shape of the bioactive food complex to complement the feeding mechanism and behavior of the aquatic animal target species (p. 17, 1st and 2nd paragraphs). In particular, Villamar teaches the production of particles in the size range of about 20-200 μm for small/larval animals and particles from about 100-1000 μm for larger/postlarval animals. Villamar also teaches the use of bioattractants (p. 11, top paragraph), rendering claim 123 obvious.

13. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include known probiotic bacteria such as *Bacillus* spp. in the compositions of Kürzinger. One would have been motivated to do so since Villamar teaches that probiotic bacteria are advantageous for controlling bacterial disease in aquaculture. Based on Villamar's teachings, it also would have been *prima facie* obvious to adjust the particle size of the compositions (including particles of about 150 μm) and include a bioattractant as needed to feed any cultivated aquatic animal, as would be recognized by the ordinary artisan. Further, one would have had a high expectation of success in doing so since the compositions of

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Villamar comprise alginate, other non-digestible polymers, and lecithin as do those of Kürzinger. Thus, the combination of Kürzinger, Nakatsuka, and Villamar renders obvious claims 87, 97-100, 103, 105-107, 113, 115, and 116.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicant argues that Villamar does not teach a starch-emulsifier complex (response, p. 11).

It is noted that the term "complex" has not been given a special definition in the instant application. Thus, the term can be interpreted broadly. Webster's dictionary defines a "complex" as, *inter alia*, 1) an association of related things often in intricate combination, and 2) a conjunction of varied contributing or interacting factors, elements, or qualities. The compositions of Kürzinger and Nakatsuka, which comprise alginate,

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high-amylose starch, and lecithin (i.e. an emulsifier) (i.e. all the components required of the instant compositions) fall within this definition and thus can be considered to comprise a starch-emulsifier complex. Thus, this aspect of applicant's claimed invention is taught by both Kürzinger and Nakatsuka.

NEW GROUNDS OF OBJECTION/REJECTION

Claim 103 is objected to because of the following informalities: the word "processes" should be "processed". Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

Claim 95 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Amended claim 95 recites the limitation, "...wherein dissolved starch granules are formed when the starch complexes with the emulsifier in alkali solution". This limitation is indefinite because it is unclear whether the claim requires the formation of granules or the dissolution of granules. Is the starch dissolved (i.e. granules are absent) or are granules present? If granules are intended to be present the word "dissolved" should be deleted to remove the ambiguity in the claim. The metes and bounds of the claim are presently unclear.

Summary/Conclusion

Claims 90-95 and 103 are objected to; claims 87-100, 103-116, and 121-123 are rejected; claims 1-86 are cancelled.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643